510(k) Summary

Submitter Information	Company:	The Anspach Effort, Inc. 4500 Riverside Drive Palm Beach Gardens, FL 33410
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	Date Prepared:	November 8, 2013
Identification of the Device	Common Names:	Pneumatic and Electric Surgical Instruments and Attachments
	Device Name:	ANSPACH® XMax Pneumatic and eMax 2 and eMax2 Plus Electric Systems with the ANSPACH® Otologic Curved Micro (OCM) Attachment and OCM Burr Support Sleeves
	Classification Names:	• Ear, nose and throat electric or pneumatic surgical drill • Ear, nose and throat bur
	Device Classification:	• Class II, 21 CFR 874.5250 (drill) • Class I, 510(k) exempt, 21 CFR 874.4140 (bur)

Predicate Devices(s)

The subject devices are substantially equivalent to the following predicate devices:

The electric and pneumatic surgical drills are identical to the currently marketed electric and pneumatic surgical drills:

- ANSPACH® XMax Pneumatic System cleared via K965080
- ANSPACH® eMax 2 and eMax2 Plus Electric Systems cleared via K011444

The Otologic Curved Micro (OCM) Attachment and OCM Burr Support Sleeves are substantially equivalent to the handpiece and burrs associated with the:

- Medtronic, Inc., XPS® 3000 System cleared most recently via K073255 on March 24, 2008

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Description of Device

The ANSPACH® XMax Pneumatic and eMax 2 and eMax2 Plus Electric Systems are surgical drills that handle a complete range of surgical procedures ranging from power demanding applications to the most delicate dissection.

The ANSPACH® Otologic Curved Micro (OCM) Attachment consists of the attachment which connects directly to the ANSPACH® XMax Pneumatic and eMax 2 and eMax2 Plus Electric Systems handpieces with the standard twist lock mechanism, and the OCM Burr Support Sleeves. The OCM is provided non-sterile and is reusable. Cleaning and sterilization instructions are provided in the ANSPACH® OCM Attachment package insert.

The ANSPACH® OCM Burr Support Sleeves with integral cutting burrs mount to the OCM Attachment with a simple snap-in connection. The 20° curve and small diameter of the OCM Burr Support Sleeves provides excellent visibility. The non-rotating support sleeve protects soft tissue from the rotating cutting burr shaft. The OCM Burr Support Sleeves can be used at speeds from 10,000 to 80,000 rpm. They are available in two lengths (5.6 and 7.3 cm), each with a wide variety of different cutting burr styles and diameters to accommodate varying surgeon preferences. The OCM Burr Support Sleeves are provided sterile and for single use only.

Indications for Use

The ANSPACH® XMax Pneumatic and eMax 2 and eMax2 Plus Electric Systems are intended for cutting and shaping bone including spine and cranium.

When used with the ANSPACH® Systems, the OCM Attachment and OCM Burr Support Sleeves are intended for cutting and shaping bone primarily in otology procedures such as cochleostomies.

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Technological Characteristics

There are no new technological characteristics associated with the ANSPACH® Pneumatic and Electric Systems, the OCM Attachment and the OCM Burr Support Sleeves. The ANSPACH® XMax Pneumatic and eMax 2 and eMax2 Plus Electric Surgical Drills are identical to the currently marketed electric and pneumatic surgical drills.

The new ANSPACH® Otologic Curved Micro (OCM) Attachment and OCM Burr Support Sleeves utilize the same biocompatible materials as currently marketed attachments and burrs. The packaging, manufacturing method, and cleaning and sterilization methods of the OCM Attachment are the same as currently marketed ANSPACH® attachments. The OCM Burr Support Sleeves packaging, manufacturing method and sterilization method are also the same as currently marketed ANSPACH® burrs.

The new indications for use are consistent with numerous other currently marketed surgical drill systems and accessories.

Non-Clinical Testing

A series of biocompatibility tests demonstrated the safety of the OCM Burr Support Sleeves patient contacting materials. All tests were conducted in accordance with the GLP regulation (21 CFR Part 58).

Several performance tests demonstrated the safety and effectiveness of the OCM Attachment and OCM Burr Support Sleeves. Specifically, OCM Attachment testing demonstrated proper functionality after repeated use, safe external temperatures, and the ability to clean and sterilize effectively without adverse effects on functionality or performance. OCM Burr Support Sleeves testing demonstrated proper functionality and safe external temperatures. In addition, a simulated use study demonstrated both the OCM Attachment and the OCM Burr Support Sleeves perform as intended in cutting and shaping bone properly.

Conclusions

Scientifically valid data demonstrates that the ANSPACH® XMax Pneumatic and eMax 2 and eMax2 Plus Electric Systems with the ANSPACH® Otologic Curved Micro (OCM) Attachment and OCM Burr Support Sleeves is as safe and effective as the predicate devices when used in accordance with the labeled directions for use and for the requested indication.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 31, 2013

The ANSPACH Effort, Inc.
% Ms. Annette M. Hillring
3012 St. Charles Drive
Tampa, FL 33618

Re: K131053
Trade/Device Name: ANSPACH® XMax Pneumatic and eMax 2 and eMax2 Plus Electrical Systems with Otologic Attachment System (Otologic Attachment and Curved Burrs)
Regulation Number: 21 CFR 874.4250
Regulation Name: Ear, Nose and Throat Electric or Pneumatic Surgical Drill
Regulatory Class: Class II
Product Code: ERL; EQJ
Dated: November 26, 2013
Received: December 2, 2013

Dear Ms. Hillring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: Registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bradley S. Cunningham -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _K131053_

Device Name: ANSPACH® XMax Pneumatic and eMax2 and eMax2 Plus Electrical Systems with Otologic Attachment System

Indications for Use: The ANSPACH® XMax Pneumatic and eMax 2 and eMax2 Plus Electric Systems are intended for cutting and shaping bone including spine and cranium.

When used with the ANSPACH® Systems, the OCM Attachment and OCM Burr Support Sleeves are intended for cutting and shaping bone primarily in otology procedures such as cochleostomies.

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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